Re-Engineering Clinical Research Through the Clinical and Translational Science Awards: Potential Benefit for Development

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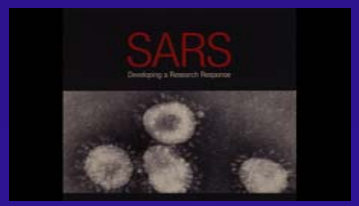
Public Health Challenges

Acute to chronic conditions

Aging Population

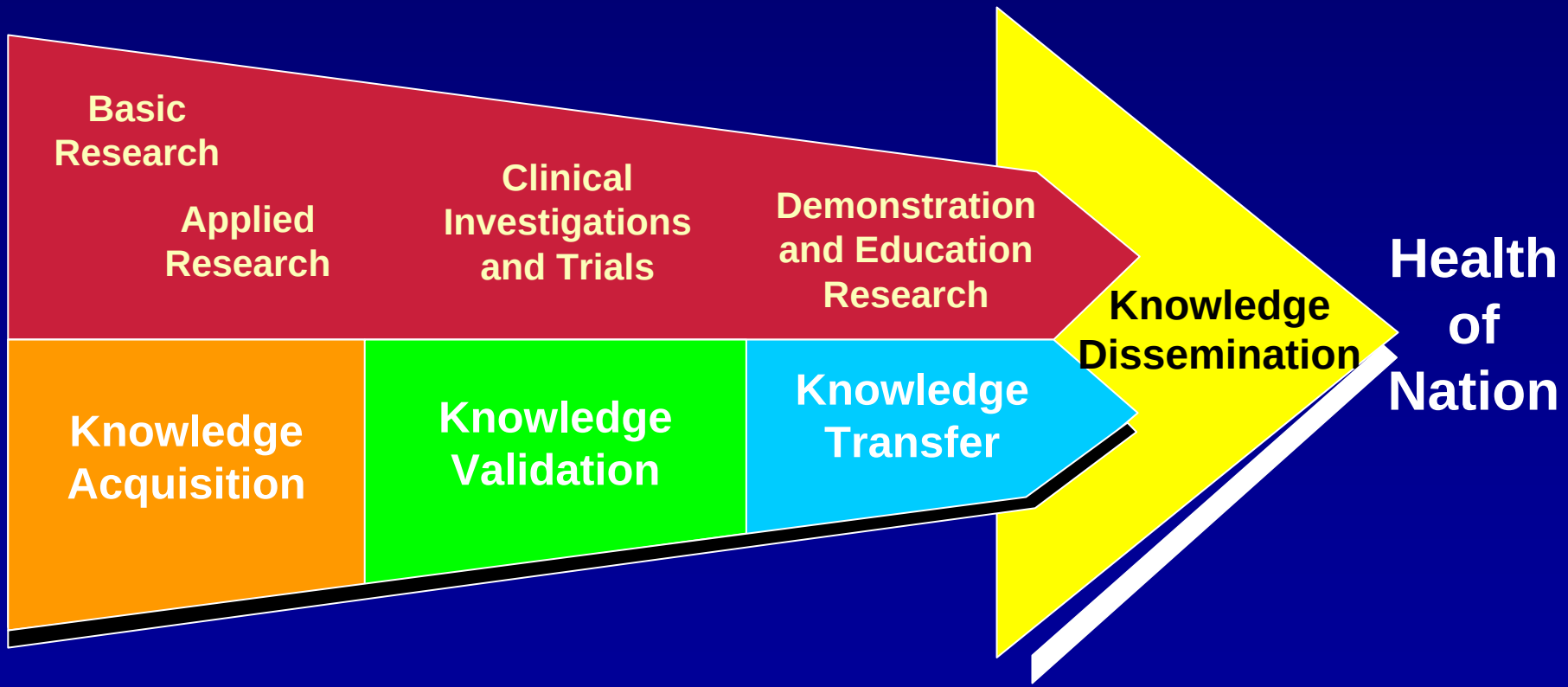
Health Disparities



Emerging Diseases

Biodefense

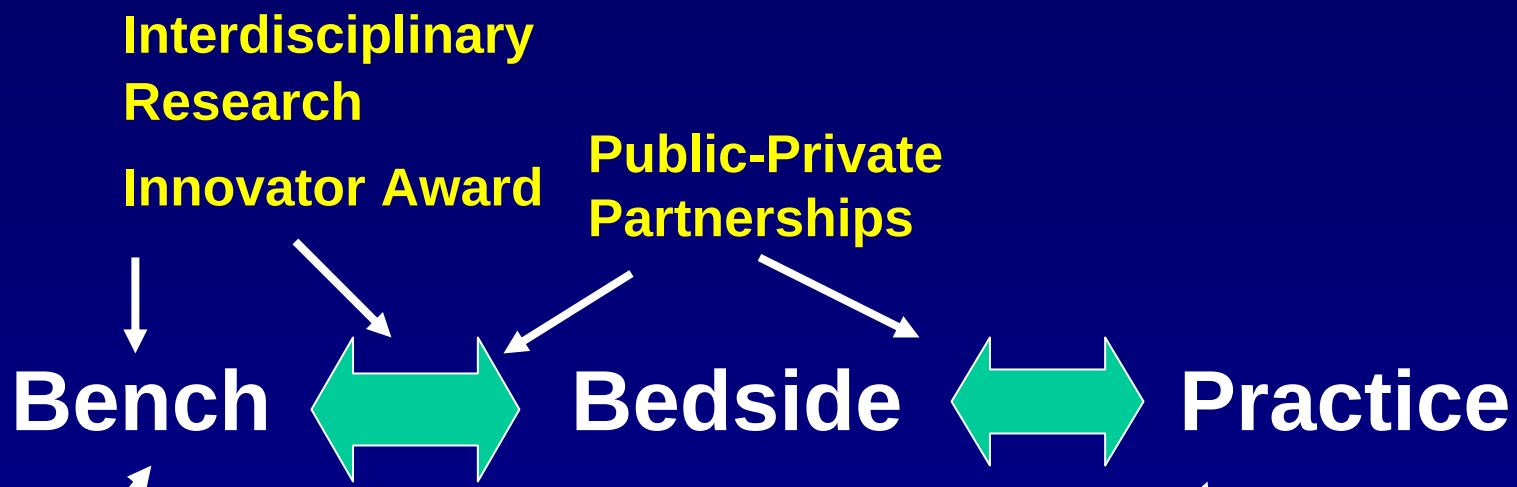
The Research Enterprise



Why a Roadmap?

- Accelerated pace of discoveries in the life sciences
- Need for their more rapid translation into practice
- Opportunities to build an integrated system that is far more effective than current approaches

Re-engineering Clinical Research



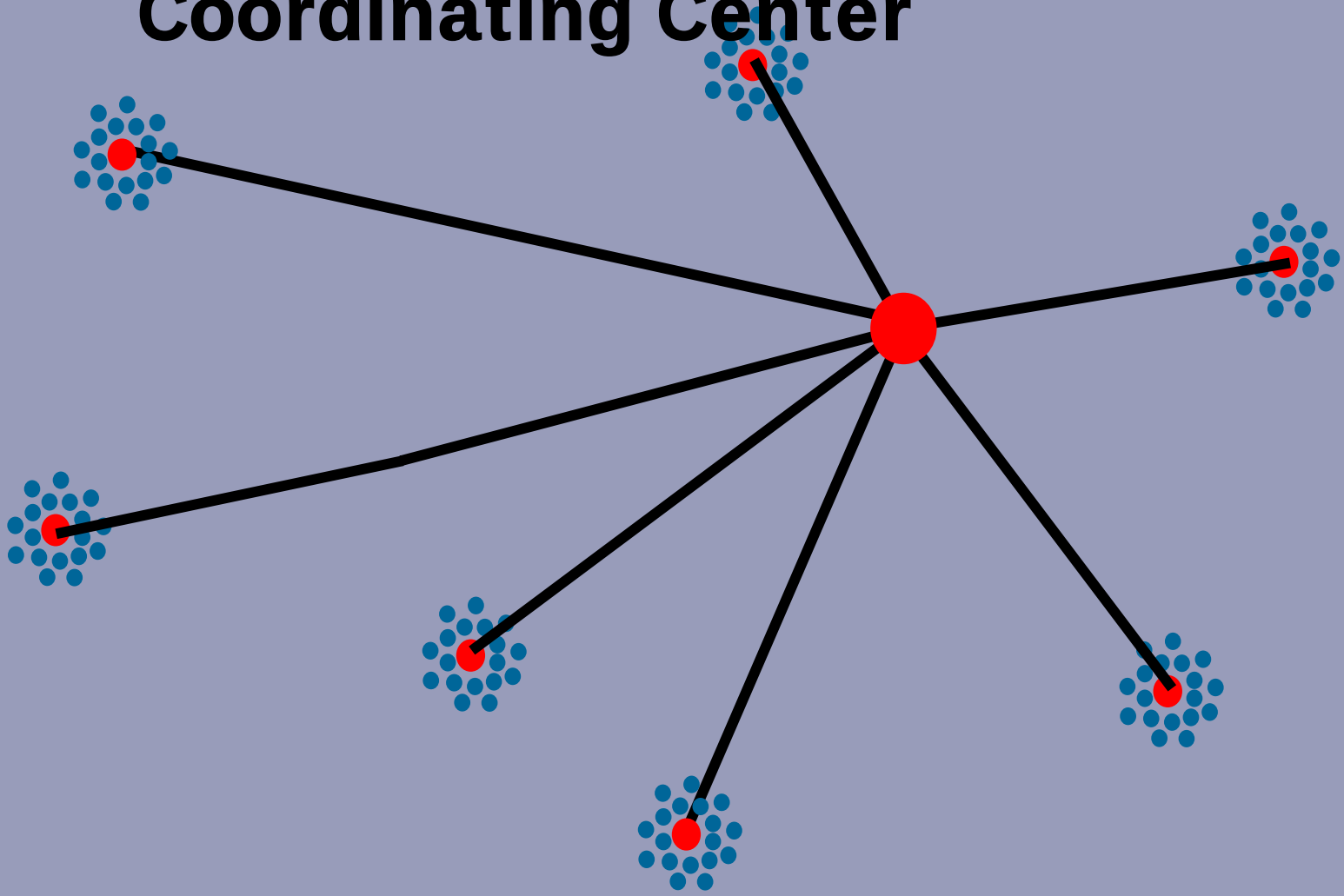
Building Blocks and Pathways
Molecular Libraries
Bioinformatics
Computational Biology
Nanomedicine

Translational Research Initiatives

Integrated Research Networks
Clinical Research Informatics
NIH Clinical Research Associates
Clinical outcomes

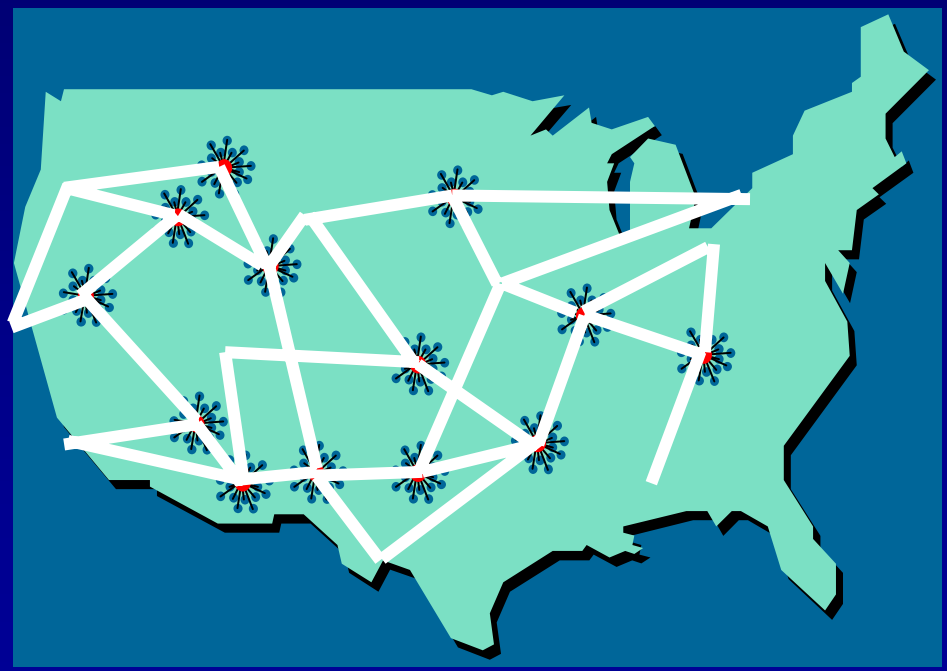
Cross cutting: Harmonization, Training

Typical NIH Network Academic Health Center Sites & Data Coordinating Center

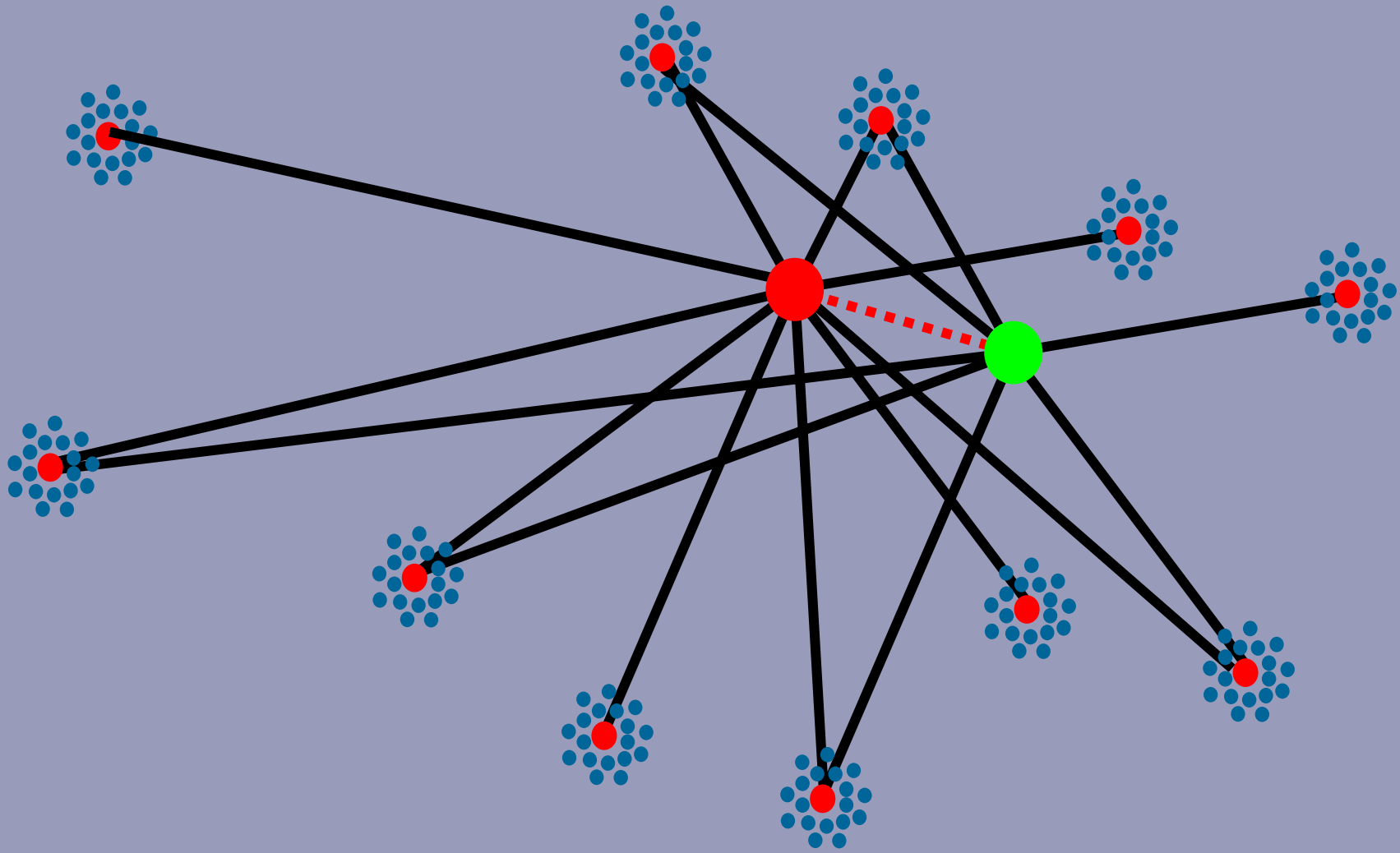


Integration of Clinical Research Networks

- Link existing networks so clinical studies and trials can be conducted more effectively
- Ensure that patients, physicians, and scientists form true “Communities of Research”



Interoperable Networks Share Sites and Data



Re-engineering the Clinical Research Enterprise: Proposal

FY2004 - FY2006

Inventory and Evaluation of Clinical Research Network
$4.6M (18 months)

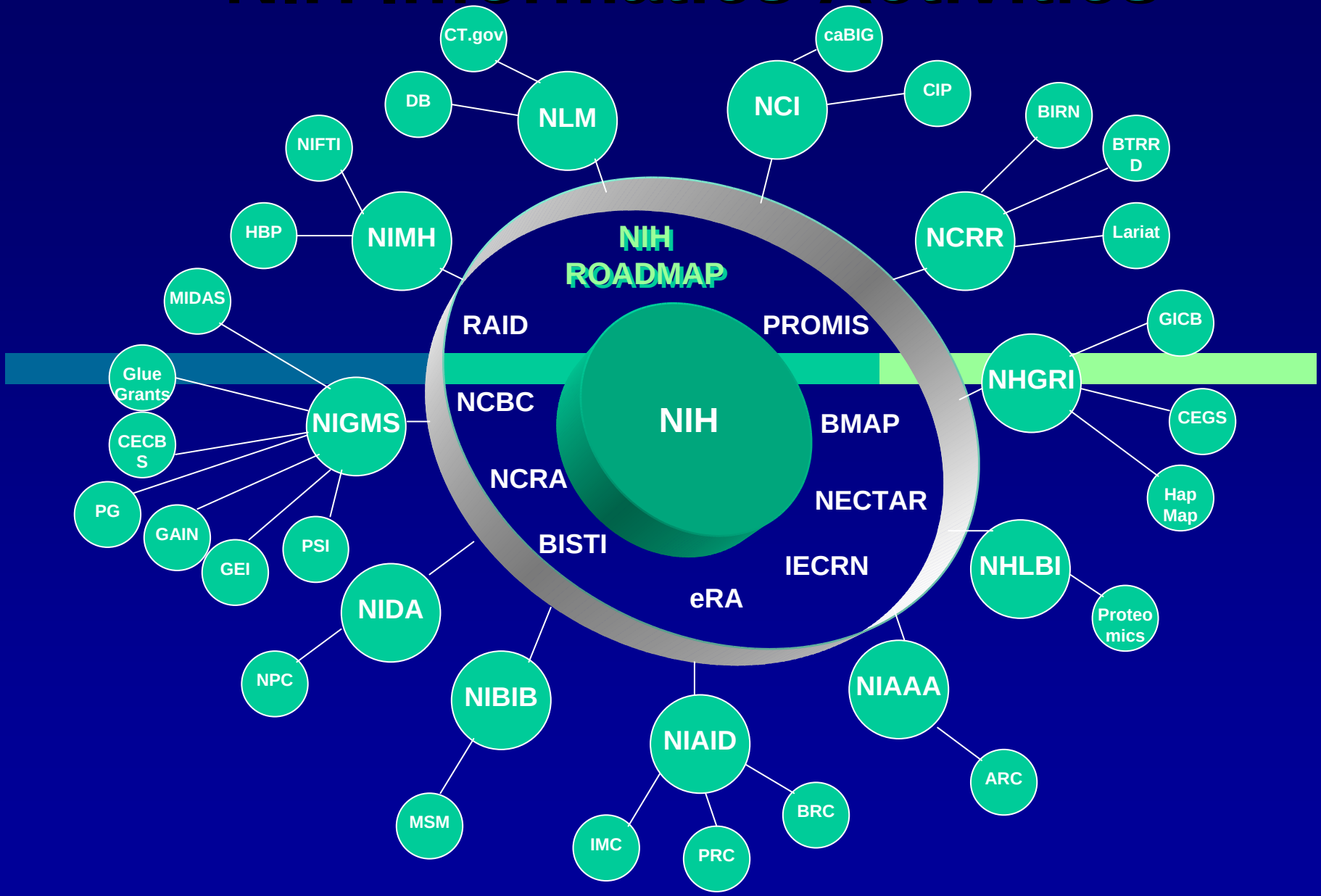
Feasibility of Integrating and Expanding Clinical Research Networks
$34.4M (3 years)

FY2007-

Incorporate our acquired knowledge into a focused, accelerated initiative to achieve measurable benefits in clinical research, and in public engagement.

Work closely with CTSA, caBIG, BIRN, NHIN, Health IT. Track, influence & exploit evolving standards and tools.

NIH Informatics Activities



Stakeholders

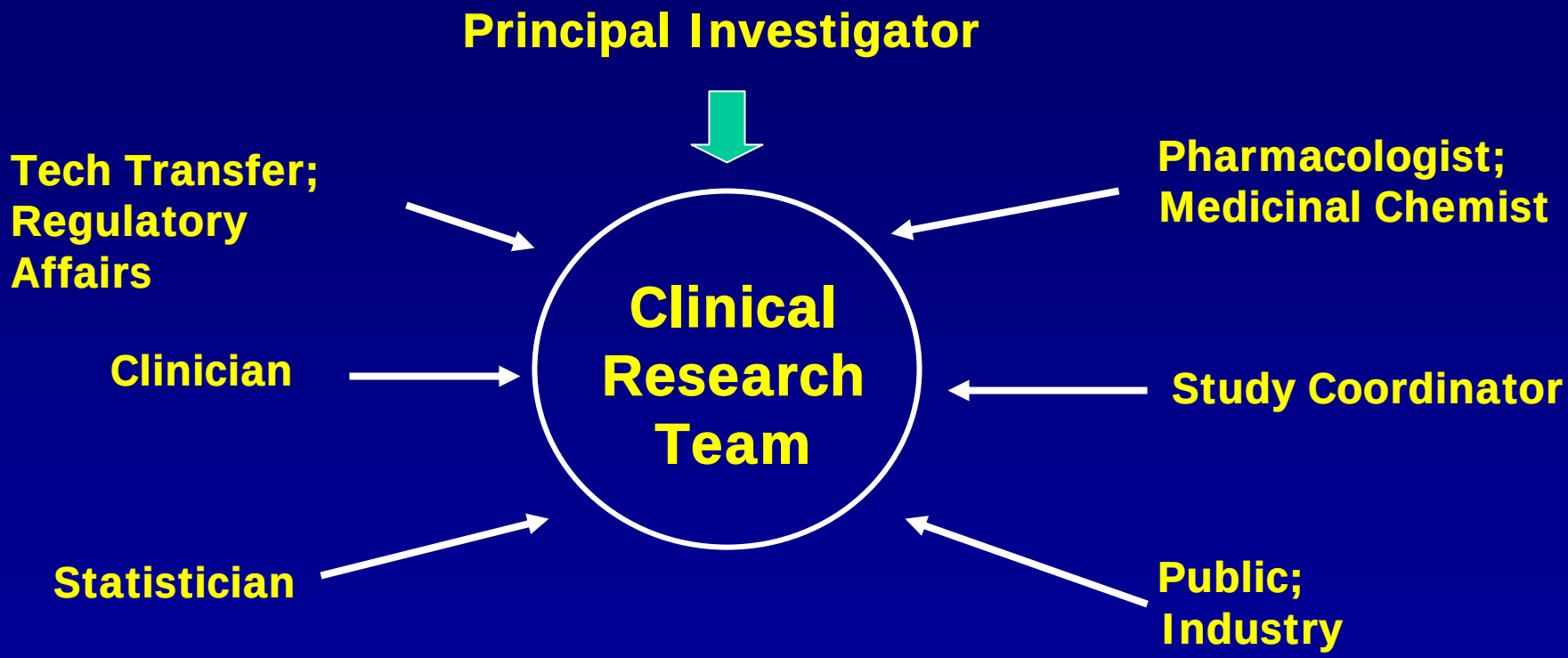
- Industry: pharmaceutical, device, hospitals, labs, health IT, CRO, insurance
- Federal: CMS, VA/DoD, FDA, ONC, AHRQ, HRSA, IHS, CDC, NIH, DHS
- Public: Physicians, patients & participants

Measurable Results

- Reduction in clinical research: cost, startup time, overall duration, duplication
- Increased public awareness, trust and participation in clinical research
- Enhanced access of clinical research data by researchers & regulatory organizations.

Multidisciplinary Clinical Research Team

Members have unique skills and career paths



Priority Issues

1. Diverse adverse event reporting requirements
2. Confusion regarding roles and responsibilities of Data Safety and Monitoring Boards, IRBs, and other review mechanisms
3. Variable requirements for auditing and monitoring of clinical trials
4. Absence of uniform standards for electronic submission of safety and clinical research information

Harmonization of Clinical Research Regulatory Processes

- Harmonize and simplify requirements for clinical research in ways that enhance public trust
  - Adverse event reporting
  - Human subjects protection
    - DSMB-IRB interactions
    - Consent procedures
  - Auditing and monitoring clinical trials
  - HIPAA, privacy, conflict of interest policies
  - Investigator registration, financial disclosure
  - Standards for electronic data submission/reporting

Outcomes

- Clear, effective, and coordinated rules for clinical research
- Maximally effective human subjects protections
- More comprehensive analysis and sharing of research data
- Enhanced quality and productivity of the research enterprise

Major Shifts in Priorities at AHCs

- Explosion in clinical service demands and reduction in financial margins side-lines the training of clinician scientists
- Marked increase in numbers of faculty leads to a “dilution” effect with a decreasing valuation attached to translational and clinical sciences
- The complexity of knowledge needed to be an effective translational scientist is not easily acquired
- Young clinical faculty have trouble finding a real “HOME” for their aspirations

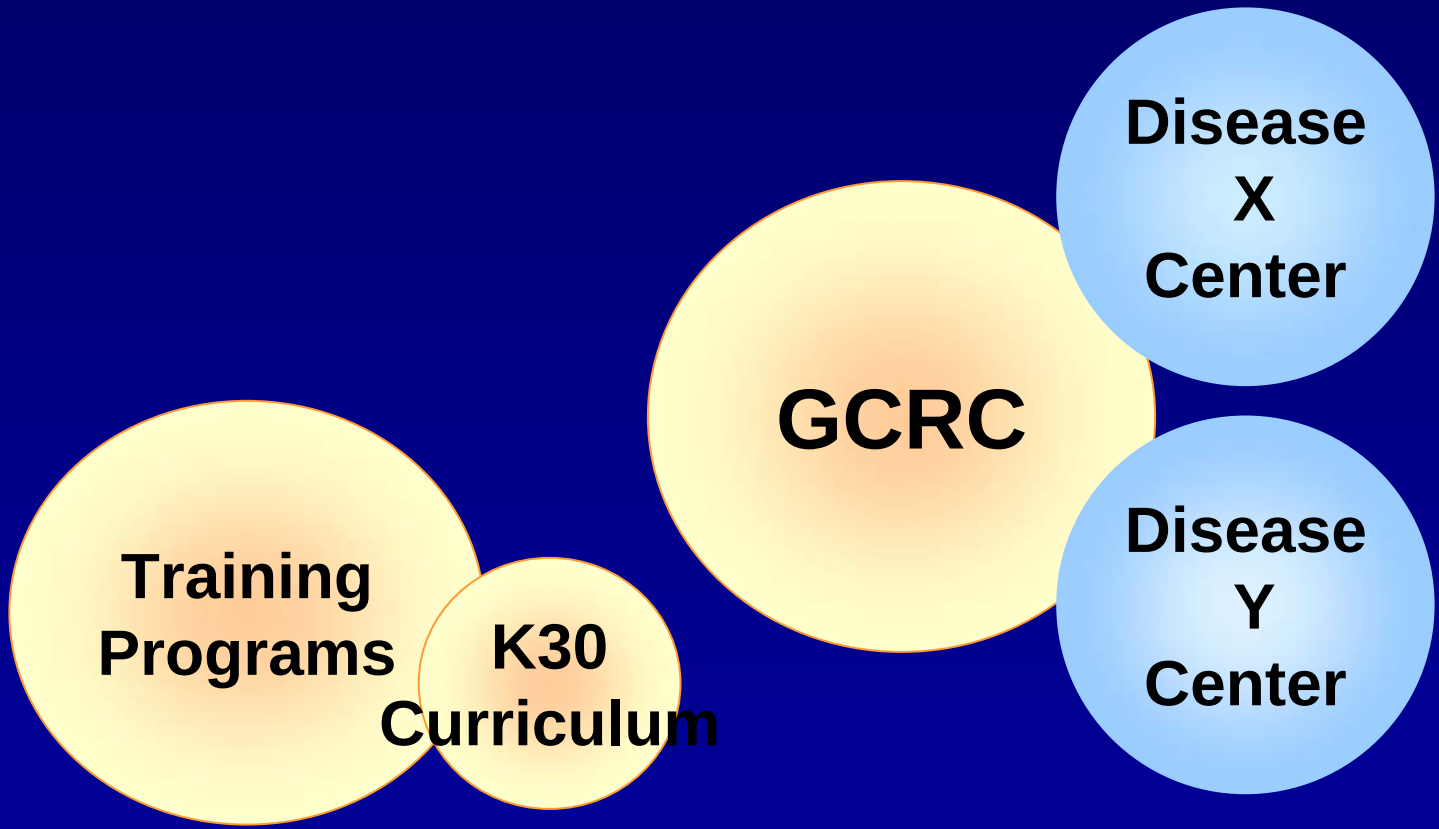
A transforming goal:

Provide the academic home and integrated resources needed to advance the new intellectual discipline of clinical and translational sciences, create and nurture a cadre of well-trained investigators, and advance the health of the nation by transforming patient observations and basic discovery research into clinical practice

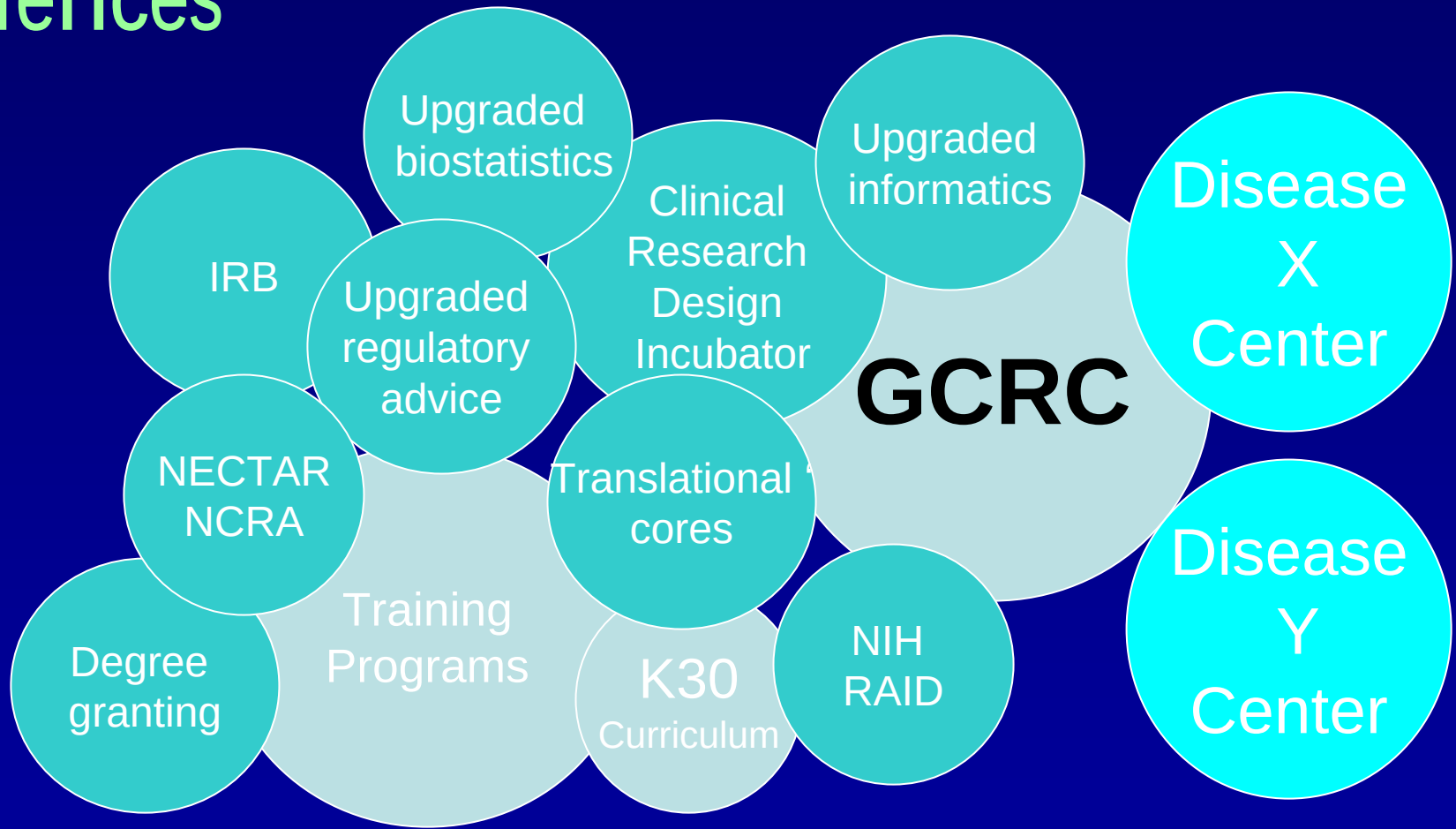
Translational Science Awards (CTSA)

- Implementing biomedical discoveries made in the last 10 years demands an evolution of clinical science
- New prevention strategies and treatments must be developed, tested, and brought into medical practice more rapidly
- CTSA awards will lower barriers between disciplines, and encourage creative, innovative approaches to solve complex medical problems
- These clinical and translational science awards will catalyze change -- breaking silos, breaking barriers, and breaking conventions

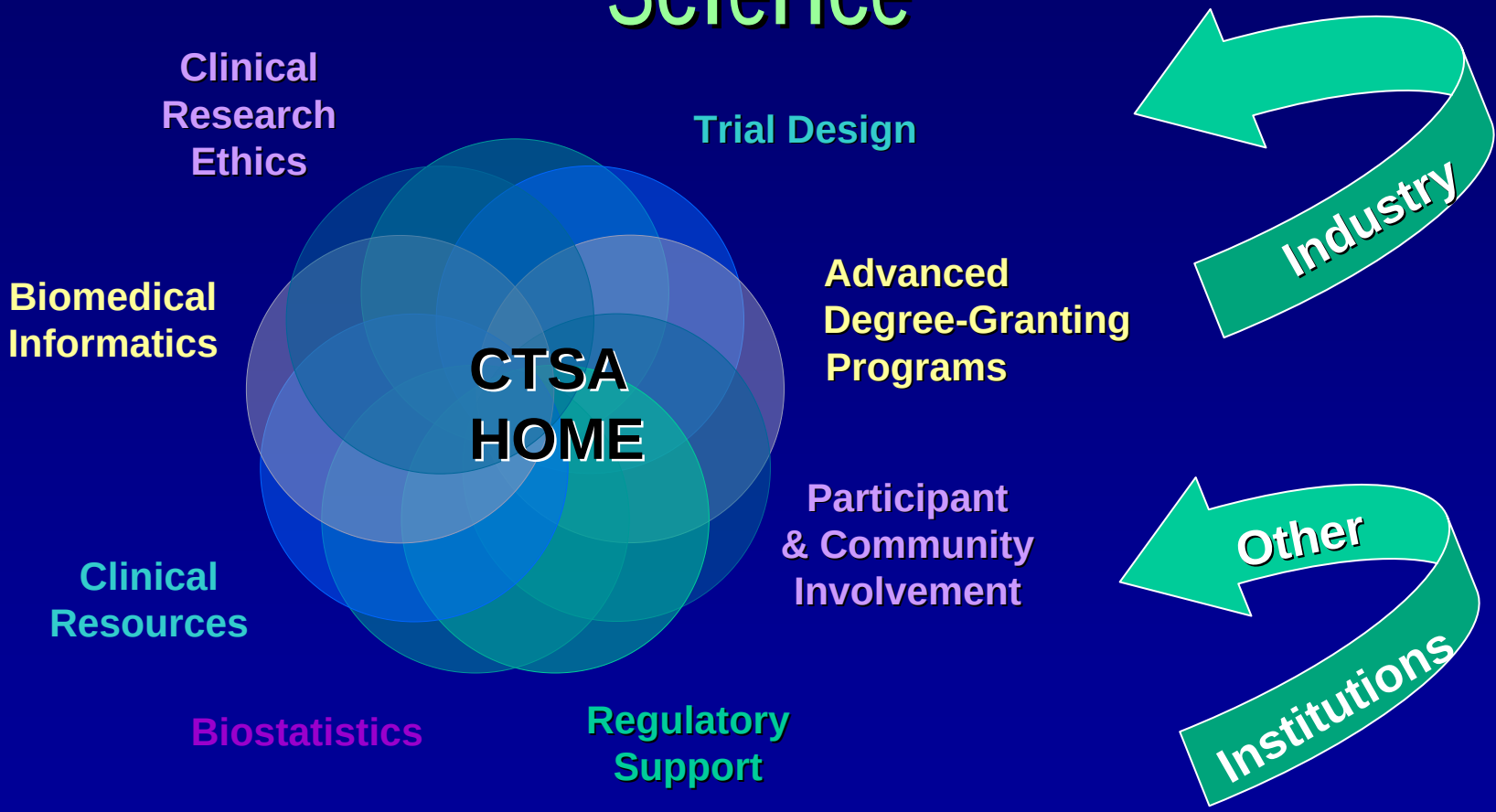
Where are we starting from?



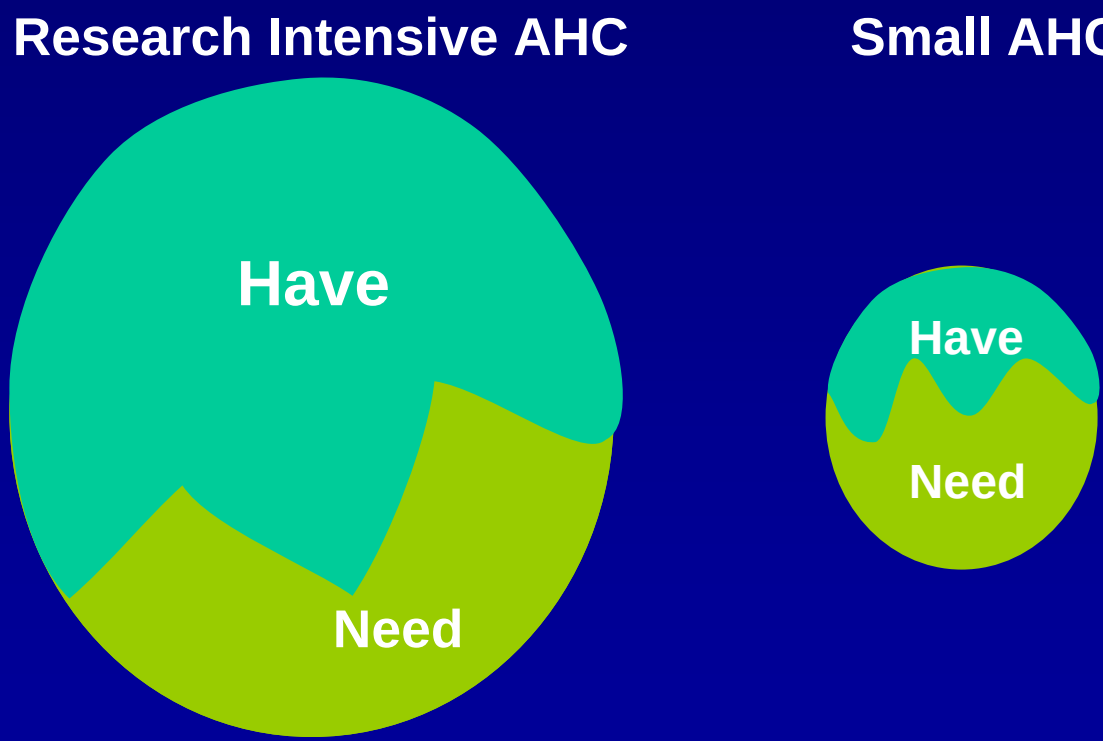
Missing Pieces needed to form a Home for Clinical and Translational Sciences



NIH CTSA Awards: A Home for Clinical and Translational Science



New programs will support different experimental models and approaches



Flexible programs with adjustable sizes for different needs

How is this transformation achieved?

- Through the NIH Roadmap for Medical Research, create an integrated environment for the clinical and translational researcher that can provide:
  - **an academic home for clinical research (a Center, Department, or Institute [C/D/I])**
  - **support for protocol preparation, regulatory compliance and data management**
  - **support for participant recruitment, human subject safety monitoring**
  - **education leading to advanced degrees in clinical research**
  - **specialized cores and services for translational research**

Definitions

Clinical Research covers all studies of diseases and trials of treatments that take place in human subjects

Translational Research describes the steps between a fundamental discovery and its application in clinical medicine.

CTSA Eligibility

- **Domestic institutions, universities, academic health centers, or other organizations conducting clinical and translational research.**
- **Partnerships with independent and other research institutions are strongly encouraged.**
- **Institutions can only submit, or be part of, a single application.**

CTSA Eligibility

A graduate school accredited to award higher degrees in clinical research must be included.

- The graduate school could be at an affiliate rather than the applicant institution. Prior awarding of higher degrees in clinical research (MS, PhD) is expected.
- By requiring a degree-granting academic program, NIH expects to create en environment that will foster the development of clinical and translational science as a distinct discipline

FY2006 CTSA Funding Opportunities

- RM-06-002: Institutional Clinical and Translational Science Award RFA

- RM-06-001: Planning Grant RFA for Institutional CTSAs
  - Allows more time to prepare a CTSA application
  - One time solicitation for one-year award
  - ~50 awards, $150K direct costs; $11.5 M total

More Information

http://nihroadmap.nih.gov